



# Levelling the Playing Field: the FDA's Regulation of Nicotine Dependence Products

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Leveling the Playing Field:  
The FDA's Regulation of Nicotine Dependence Products

J. Szubin  
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& Drug Law

The Federal Food and Drug Administration's decision in 1996 to regulate cigarettes as nicotine-delivery devices was one of its most celebrated actions in recent history. Newspapers, health experts, and the public applauded the FDA for taking on the mighty tobacco industry that had resisted serious regulation since this nation's inception. Many wondered, however, what had prompted this new course of action. After all, the FDA had considered regulating tobacco several times before and had always declined on the grounds that tobacco companies did not make health claims for their products, and that they therefore were not products "intended to affect the structure or function of the body." While the FDA justified its change of course with reference to new evidence on the dangers of cigarettes and the state of cigarette manufacturers' knowledge, the agency could not have been greatly surprised by evidence of either. What, in fact, had changed was the FDA itself – its leadership had become much more aggressive in trying to intervene and slow the devastating mortality rates from smoking-related illnesses.

To achieve its goals of regulating cigarettes – especially the advertising and sale of cigarettes to minors – the FDA employed a flexible approach. First, it adopted an expansive reading of the term "intended," examining the subjective intent of the product's manufacturers and the state of mind of its consumers rather than the product's advertised claims. Once it established jurisdiction, the agency again took an unorthodox approach, declining to classify cigarettes as either a controlled substance or a drug, and instead employing a very flexible reading of the term "device," to classify tobacco as a "nicotine-delivery device."<sup>1</sup> Finally, the FDA has delayed placing tobacco into a class of device, a move which would severely circumscribe the agency's freedom to tailor its regulatory responses to future developments.

Commentators have differed about the wisdom of the FDA's specific policy choices. And the courts have

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<sup>1</sup>Nicotine in Cigarettes and Smokeless Tobacco Is a Drug and These Products Are Nicotine Delivery Devices Under the Federal Food, Drug, and Cosmetic Act: Jurisdictional Determination, 61 Fed. Reg. 44,619 (1996).

not been receptive to the FDA's defense of its jurisdiction over cigarettes.<sup>2</sup> But, at the very least, the FDA deserves credit for stepping into a critical health battle that was thought to be unwinnable, and for showing enormous resourcefulness and flexibility in crafting a regulatory approach that was well suited to this uniquely difficult problem.

Unfortunately, the FDA has not shown the same kind of flexibility and far-sightedness in regulating products that are targeted at nicotine dependence. These nicotine dependence products (NDPs) could be of great help in the FDA's war on smoking-related illness, as they are capable of providing the treatment arm of a treatment/prevention attack, that would be maximally effective in reducing the death toll of tobacco.

## The Problem

Tobacco is the most deadly substance in America, accounting for one in five deaths in the U.S.<sup>3</sup> – more than AIDS, car accidents, alcohol, homicides, illegal drugs, suicides and fires combined.<sup>4</sup> Tobacco related illnesses claim the lives of approximately 400,000 Americans each year and it is projected that the number will remain steady for “several decades to come.”<sup>5</sup> Scientists predict that close to half of addicted smokers will die prematurely.<sup>6</sup> With 50 million smokers currently, that translates to 25 million premature deaths yet to come.

If there is any ray of hope in this bleak area, it is that pharmaceutical companies have had increasing

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<sup>2</sup>A federal district court struck down the FDA's advertising regulations as exceeding the agency's statutory powers. See *Coyne Beahm, Inc. v. U.S. Food & Drug Admin.*, 966 F. Supp. 1374 (M.D.N.C. 1997). On appeal, the Fourth Circuit struck down the entire 1996 ruling as inconsistent with the FDA's enabling statutes. See *Brown & Williamson Tobacco Corp. v. Food & Drug Admin.*, 153 F.3d 155 (4<sup>th</sup> Cir. 1998).

<sup>3</sup>John Slade & Jack E. Henningfield, *Tobacco Product Regulation: Context and Issues*, 53 FOOD & DRUG L.J. 43, 43 (1998).  
<sup>4</sup>Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents, 61 Fed. Reg. 44,396, 44,398 (1996).

<sup>5</sup>Jack E. Henningfield & John Slade, *Tobacco-Dependence Medications: Public Health and Regulatory Issues*, 53 FOOD & DRUG L.J. 75, 75 (1998).

<sup>6</sup>*Id.*

successes in developing products to help addicted smokers reduce or eliminate their tobacco habits. Since the development of the nicotine gum in 1984, pharmaceutical companies have produced several variants of gums and patches, as well as a nicotine nasal spray and an anti-depressant medication, bupropion, which have proven successful, to varying degrees, in helping smokers overcome their nicotine addictions. In 1996, the same year as the FDA's famous tobacco ruling, the FDA approved over-the-counter sale of one brand of nicotine gum (Nicorette) and two brands of nicotine patch (Nicotrol and Nicoderm). It also approved the sale by prescription of a nasal spray and vapor inhaler and Zyban, a brand of bupropion hydrochloride, marketed as a smoking cessation medication.

These products are far less dangerous than the products they seek to replace. The most obvious advantage of the NDPs is that they eliminate the dangers posed by external contaminants in tobacco products. In the case of cigarettes these contaminants cause lung cancer and in the case of cigars and chewing tobacco they may cause lip or mouth cancer. Moreover, NDPs have been shown to pose a substantially lower risk of cardiovascular disease than do cigarettes.<sup>7</sup>

Even if one considers the nicotine delivered by NDPs as compared with tobacco products, NDPs are significantly safer. Nicotine is a drug, and it is highly addictive.<sup>8</sup> But the addiction potential of any nicotine delivery system is a product of several factors, including the amount of nicotine dispensed, the speed with which it is absorbed, the ease with which it can be accessed, and the product's sensory characteristics (such as its flavor and general use appeal).<sup>9</sup> NDPs are preferable to cigarettes in each of these areas. Indicated use of NDPs will administer lower doses of nicotine than cigarettes, with little potential for overdosing.<sup>10</sup> NDPs

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<sup>7</sup>Id. at n102 (citing several studies, which support the conclusion that "use of nicotine transdermal systems place patients at substantially lower risk [for] cardiovascular events than cigarette smoking.")

<sup>8</sup>Id. at 81.

<sup>9</sup>Id. at 82.

<sup>10</sup>The exception is nicotine nasal spray, which delivers a quick dose of nicotine and can easily be abused by consumers.

are also slower to work than cigarettes, with lung inhalation being the single fastest way to intake nicotine. In the case of nicotine gum, to access nicotine a person must keep the gum in his or her mouth for a period of fifteen to thirty minutes, alternating between active chewing and “parking” the gum passively in the mouth. With a transdermal patch, speed and dose are regulated, with the patch administering a steady low dose of nicotine throughout the day. Breaking an addicted smoker away from the cycle of “craving-cigarette-quick fix” is a major contributor to the success of NDPs in weaning a smoker away from nicotine addiction. Finally, the NDPs have less appealing sensory traits than do cigarettes or other tobacco products. Most have no taste whatever, and nicotine gum is intentionally given a palatable but not appealing taste (described as “peppery”). Moreover, there is, as of yet, no social caché associated with any of the NDPs – to the contrary, there may be a social stigma attached to their use.

It is because NDPs are less addictive in all of these ways that they can serve as a powerful tool in an individual’s efforts to quit smoking. As a result of the lower dose or slower release and the conditioning away from the behavior of smoking,<sup>11</sup> quitting is made easier. In clinical studies, treatment programs administering NDPs have allowed approximately 20% more smokers to quit for periods of a year or more.<sup>12</sup> And tests on bupropion, one specific NDP, have shown that almost twice as many smokers are able to maintain abstinence over a year with the aid of the product.<sup>13</sup> These statistics lend support to the finding that between 114,000 and 304,000 more smokers a year are able to quit for at least one year due to the recent over-the-counter availability of nicotine patches and gum – an increase of between 10-25 percent over previous levels.<sup>14</sup>

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<sup>11</sup>Nicotine vapor inhalers are an exception as far as smoking behavior goes. Inhalers are specifically designed to mimic the hand-to-mouth motions of smoking for smokers who are unable to adapt to other NDPs.

<sup>12</sup>Henningfield & Slade, *supra* note 5, at 78-9.

<sup>13</sup>Richard D. Hurt et al, *A Comparison of Sustained-Release Bupropion and Placebo for Smoking Cessation*, 337 NEW ENG. J. MED. 1195 (1997).

<sup>14</sup>Henningfield & Slade, *supra* note 5, at 101-02, n131.

Given the enormous health risks posed by cigarette addiction and the proven efficacy of NDPs, the current regulatory approaches towards tobacco products and NDPs are baffling. Tobacco manufacturers, even under the 1996 ruling, are able to label, market and advertise their products with great flexibility, while pharmaceutical companies that manufacture NDPs must follow the strict guidelines laid out for the labeling and marketing of drugs. Only two NDPs are available over-the-counter, while every tobacco product from snuff to cigarettes can be purchased without a prescription. Even the over-the-counter NDPs are only available in pharmacies and large supermarkets. Cigarettes, though no longer sold in vending machines, are still available at every corner grocer and newsstand.

As drugs, the labeling, marketing, and advertising of NDPs are strictly regulated by the FDA. The over-the-counter NDPs are labeled like any other medication, prominently listing their active ingredients, indications, and side-effects. They are sold in large white boxes, with little color, and no figures or designs. And their advertisements must include a list of indications and possible side effects. Tobacco products, while not allowed access to FCC media, advertise in print media, billboards, and storefront signs with alluring photographs of young models, cowboys, and hip urban scenes.<sup>15</sup>

Perhaps most striking, though, is the regulation of health claims made by NDPs as compared with their less safe competitors. Tobacco companies are permitted to claim that their products will reduce a smoker's exposure to tar or nicotine based on a test that is widely known to be flawed. The FTC Cigarette Test Method was developed in the 1960s and is still used today to measure a smoker's intake of tar and nicotine from cigarettes. The test employs a machine that "puffs" on a cigarette a specified number of times for a set number of seconds. Numerous studies have found that the levels of nicotine and tar measured by this test are

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<sup>15</sup>The FDA sought to significantly delimit the bounds of cigarette advertisements in its 1996 ruling, but those provisions are not likely to take effect, having been found to exceed the FDA's authority by both a district court and the Fourth Circuit, on appeal, for different reasons.

seriously flawed, underestimating the intake of human smokers who take longer puffs and block ventilation holes that would otherwise allow toxins to escape.<sup>16</sup> Smokers, however, eager to reduce their health risks from smoking, have unquestionably taken these claims to heart, with low tar and reduced nicotine delivery cigarettes now accounting for approximately two thirds of the cigarette market.

Meanwhile, not only do such “light” brands provide “little or no health benefit,”<sup>17</sup> they may actually harm smokers. Health claims of light cigarettes encourage smokers looking to reduce or eliminate their cigarette intake to merely switch brands, rather than pursue medications or abstinence. They may even lead to an increase in cigarette use, if smokers feel that they can safely smoke such low-tar or reduced-delivery cigarettes without the concomitant risks of smoking. And it is now known that smokers of reduced-delivery cigarettes take deeper pulls in order to compensate for the reduced nicotine delivery, which has led to a sharp increase in adenocarcinomas of the lower lung among smokers.<sup>18</sup>

It is not only tobacco products that are given substantial leeway to promote dubious health claims for their products. Several homeopathic medicines and non-restricted devices are marketed as smoking addiction cures, and are not regulated by the FDA. CigArrest, for example, is a homeopathic medicine marketed as a treatment for nicotine addiction, that is made from a combination of herbs, tree bark, and calcium phosphate. Anti-addiction devices are also sold for similar purposes, such as a pick that ventilates cigarettes so as to reduce their level of nicotine and smoke delivery. These products do not have to submit their studies to the FDA for review and are able to make broad claims about their effects. A box of CigArrest, brightly colored and labeled “The Smoker’s Choice,” boasts that the product “Reduces Irritability,” “Reduces Tobacco Cravings,” “Relieves Nervous Tension,” and “Helps Detoxify.”

The contrast with NDPs is severe. NDPs have only been approved by the FDA as smoking cessation treat-

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<sup>16</sup>Slade & Henningfield, *supra* note 3, at 49.

<sup>17</sup>*Id.* at 52.

<sup>18</sup>*Id.*



ments. These products are not allowed to address uses other than absolute cessation. For the smoker who is not ready to quit, who might be looking to reduce the number of cigarettes she smokes a day or reduce the health risks that she runs without lowering her nicotine intake, NDPs are unquestionably safer than reduced-delivery cigarettes and almost certainly more effective than homeopathic treatments. And yet, the FDA has forbidden the labeling of these products for anything but smoking cessation. In fact, warnings on the over-the-counter medications warn against continuing to smoke while using the product, effectively telling smokers who are unable to reduce their cigarette intake without assistance, to continue smoking at their current level rather than smoke fewer cigarettes with the help of a skin patch.

Moreover, if a tobacco company develops a new product with purported health advantages, it can bring it directly to market. The development and marketing of a new health claim or a new NDP, in contrast, would require onerous clinical trials, costing millions of dollars and years of research.

“Existing nicotine regulation aggravates the tobacco epidemic. It favours the most deadly nicotine delivery devices (cigarettes) and places the greatest constraints in the way of the least harmful products (pharmaceutical nicotine products). This has given a huge marketing advantage to the deadliest products, thereby expanding the tobacco epidemic.”<sup>19</sup>

The FDA’s uneven regulation of NDPs as compared with tobacco products is not the result of inattention, nor is it the product of favoritism towards the tobacco companies. These policies result from a combination of the odd place of tobacco in FDA regulation and conscious public policy decisions on the part of the FDA.

The inherent problem in this area is that tobacco came first, by hundreds of years. With its heavily entrenched position in America, a ban on smoking is implausible. The tobacco companies rightly argue that an all-out

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<sup>19</sup>Henningfield & Slade, *supra* note 5, at n12.

ban would leave tens of millions of addicted smokers with no alternative but to turn to the black market, where they would likely purchase products even more contaminated than the ones currently on the market. Even requiring a prescription to buy cigarettes would cause widespread havoc and likely result in a black market. Thus there are serious limits on the extent to which the FDA can restrict the availability of cigarettes. This has yielded the current situation where cigarettes, an admittedly lethal and addictive substance, are regulated by the FDA as a restricted device, a category that receives less stringent attention than that of drugs.

At the same time, the new NDPs are unquestionably drugs. They are “intended to affect the structure or function of the body” as treatments for nicotine addiction. As drugs, the standard regulatory approach mandates that the labeling and advertising of these products be strictly overseen.

### **Solutions to a Difficult Problem**

One proposed solution to this admittedly difficult problem is to increase the regulations of tobacco products at least to the level of NDPs. In certain areas this is a sensible solution, such as advertising and labeling. If the NDPs have to market in large unappealing boxes and list their side-effects, there is no reason that cigarettes shouldn't face the same marketing burdens.<sup>20</sup> In other areas, this suggestion is impracticable, such as prescription status.

The second route to parity, then, would be to lessen the regulatory restrictions on NDPs. If cigarettes are an unavoidable evil, we should at least allow the products aimed at treating their consequences the same access to consumers as the tobacco companies enjoy.

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<sup>20</sup>Of course the entire field of advertising regulation may be beyond the FDA's power, as the federal district court found in Coyne Beahm, 966 F. Supp. 1374.

The FDA has not been very receptive to this type of proposal. While three over-the-counter NDPs were approved in 1996, the FDA has not loosened the regulations on the development of new NDPs or the alteration of existing ones, nor has it allowed NDP manufacturers any increased flexibility in marketing, labeling, or advertising.

The FDA's stance derives less from rigid conservatism, though, than from a considered policy decision. For, while this paper has concentrated on the beneficial uses of NDPs for smokers, the FDA has to consider the impacts of NDPs on the population as a whole. All NDPs developed to date, with the exception of the anti-depressant bupropion, are nicotine delivery systems. As mentioned above, nicotine is a dangerous and addictive drug. And, while the harmful effects of NDPs may be modest compared to the effects of smoking, they pose quite a serious risk to a non-addicted smoker who abuses them. Moreover, there is always a risk that non-smokers, especially youths and adolescents, might experiment with NDPs, grow addicted to nicotine, and enter the world of tobacco. This is the real fear of the FDA – that products meant as a step-down from tobacco abuse might serve as a step-up for non-smokers.

That fear is not wholly unwarranted. NDPs have certain characteristics that might make them more appealing to a youth who would otherwise not experiment with smoking. First, despite the warnings on packages, it would be easy for a youth to assume that NDPs are fairly safe. They are FDA-approved medications and some even sport the American Cancer Society's logo on their boxes. They are advertised as aids to health, and often marketed with the tag line "ask your doctor about the benefits of \_\_\_\_\_." Even a person who understood the potential health risks of nicotine might conclude, in error, that NDPs are a good product to experiment with because they will be easy to quit at any time. Second, it is far easier to conceal the use of an NDP than it is to conceal cigarette use, which emits smoke and leaves behind a tell-tale odor. It is easily conceivable that a youth wanting to discretely experiment with nicotine would start with a gum or patch. With such concerns in mind, the FDA has approached the regulation of NDPs as if it were a zero-sum game –

to the extent that NDPs are made more widely available, addicted smokers will win and non-smoking youths will lose. I will question this assumption below. But, even granting that in some areas of NDP regulation (perhaps price) the benefit of another one hundred smokers successfully quitting will be paid for with some number of youths beginning a nicotine addiction, a policy decision still has to be made as to which health goal is more important. The FDA has consistently chosen to protect non-smokers rather than assist smokers to obtain effective treatments.

This choice may be based upon an ethical aversion to actively causing harms. The risks faced by smokers who are unable to quit will materialize without intervention; but any non-smokers who become initiated to nicotine through an NDP will have done so because the FDA actively chose to approve those products.

The more likely explanation, though, is that prevention is a goal oriented at protecting youth. It is thus a strategy with great appeal, both public and political. Publicly, even the tobacco industry has come out in favor of youth-prevention. Avoiding regulation of adult smoking also allows the FDA to steer clear of accusations of paternalism and the public fear of an outright ban on tobacco. The FDA therefore emphasizes that minors are a qualitatively different problem since they are not exercising free will when they choose to smoke. “[Y]oung people do not fully understand the serious health risks of [tobacco] products.... They are also very impressionable and therefore vulnerable to the sophisticated marketing techniques employed by the tobacco industry....”<sup>21</sup>

Thus, the 1996 FDA ruling on tobacco is solely aimed at regulating “the sale and distribution of cigarettes and smokeless tobacco to protect children and adolescents.”<sup>22</sup> It places no restrictions on the sale of cigarettes to majors, and limits its advertising regulations to billboards in the vicinity of schools and magazines with a substantial readership of minors.

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<sup>21</sup>Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents, 61 Fed. Reg. at 44398

<sup>22</sup>Id. at 44396.

Such policy decisions are sensible, if wrenching, conclusions to reach in the regulation of the tobacco industry. But, when turning to the regulation of NDPs, the focus on the younger, non-smoking population is unjustified. The FDA seems to have committed itself to a policy of cutting its losses, writing off the generation of current smokers and focusing instead on inculcating abstinence in the coming generation. These losses are too costly to bear, though, where regulation could make a difference.

There are approximately 50 million cigarette smokers in America today. Between 39.5 and 46 million of these are addicted. 400,000 of these smokers die every year – a staggering number. Perhaps these losses would be unavoidable if addicted smokers were not interested in improving their health. But, on the contrary, three-quarters of adult smokers report wanting to quit. Between 17 and 22 million make an attempt to quit each year.<sup>23</sup> Sadly, only 1.3 million of these quit attempts every year last beyond one year.<sup>24</sup> With a sick population seeking treatment, how can we fall short of making every effort to put effective addiction treatment products into these smokers' hands? Studies on bupropion have found that patients who took the medication for 6 weeks (while quitting) were nearly twice as likely to be abstinent at the end of a full year as were patients on a placebo.<sup>25</sup> Thus, widespread use of bupropion would be expected to yield about another 1.3 million successful attempts every year. And bupropion is only one of several NDPs available, each with its own particular strengths and indications. Other NDPs have also shown favorable results as compared with placebos.<sup>26</sup>

The public health benefit of increased success rates among quitting smokers would be enormous. Recent studies have shown that those who quit smoking reap benefits almost immediately, and those benefits increase with passing years as the lungs and cardiovascular systems recuperate. A study by the American Cancer

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<sup>23</sup>Henningfield & Slade, *supra* note 5, at 75.

<sup>24</sup>*Id.*

<sup>25</sup>Richard D. Hurt et al, *supra* note 13, at 1195.

<sup>26</sup>Henningfield & Slade, *supra* note 5, at 78.

Society found that within one year of quitting an average person's risk of coronary heart disease falls by one half. Within two years, the heart attack risk drops to near-normal. Within five years the risk of death from lung cancer falls almost by half. And within ten years of quitting the death rate for ex-smokers is similar to that of non-smokers.<sup>27</sup>

Thus, the benefits of getting effective NDPs into the minds and hands of smokers would be enormous. The FDA states in its ruling on tobacco that "[I]f . . . the number of children and adolescents who begin tobacco use can be substantially diminished, tobacco-related illness can be correspondingly reduced. . . ."<sup>28</sup> What they don't say is that this reduction in illness and death will not be seen for decades. The benefits of prevention accrue as adolescents and youths who might have otherwise taken up smoking begin to outlive what would have been their reduced life expectancies – a prospect still thirty to forty years away. Two scientists in this field estimate that the payoffs of an effective prevention program would first begin to reap their benefits in the early 2030s. In contrast, "the benefits of measures that reduce exposure in ongoing smokers as well as accelerate the reduction of smoking prevalence . . . would be expected to reduce tobacco-caused deaths within a few years. Ideally, expanded prevention, treatment, and tobacco control strategies would be initiated simultaneously and in a coordinated fashion."<sup>29</sup>

Youth prevention is undeniably important, but, in focusing on minors, the FDA should not lose sight of the enormous good that can be done in the coming years with prevention *and* treatment.

### **Flexible Approach To Regulating NDPs**

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<sup>27</sup>American Cancer Society study, reported on *CigArrest: Smoking Facts* (visited January 21, 1999) <<http://www.cigarrest.com>>.

<sup>28</sup>Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents, 61 Fed. Reg. at 44399.

<sup>29</sup>Henningfield & Slade, *supra* note 5, at 77-78.

What the situation calls for is some flexibility and creativity in applying the law to a tough problem. The same flexibility that the FDA exhibited in regulating tobacco in the first place, redefining “intent,” expanding the definition of “device,” and regulating in stages so as to reach marketing and advertising without having to classify and/or ban tobacco, is needed here. With such a creative approach, the FDA could revisit NDP regulation more productively.

First, it should be emphasized that the FDA’s fears of non-smokers beginning a nicotine addiction through the use of NDPs are not trivial concerns. At present, there has not been a developed study analyzing just how great those risks are. There is therefore a great need for research addressing the appeal of various NDPs to youth, both smoking and non-smoking, and the factors that correlate with use among non-smokers.

Second, even without a study, it is clear that some efforts to increase the appeal and use of NDPs will be far more likely to attract non-smokers than others. For example, it would not be advisable to eliminate the minimum age restriction on over-the-counter NDPs. Such a move would increase the potential for abuse enormously, while providing a minimal health benefit in the form of under-18 smokers who were actively seeking addiction treatment without a prescription. It would similarly not be worthwhile to improve the taste of Nicorette gum, which could easily be made to taste of cherry or bubble gum, as the slight increase in acceptance among nicotine addicts could not outweigh the increased risks in youth experimentation.

At the same time, other aspects of this problem are more appealing targets for intervention. As was discussed above, NDPs can currently only be marketed as smoking cessation aids. They may not make claims that they will help reduce cigarette usage, known as exposure reduction claims, because reduced intake of cigarette smoke has not yet been proven to be “safe” as compared to a person’s existing level of exposure. For similar reasons, physician package inserts and over-the-counter labeling instruct patients not to smoke at all while using nicotine NDPs. Thus, NDPs currently present a stark choice to smokers – go “cold turkey” or do not

use this aid.

Even smokers looking to quit would benefit from a change in labeling, allowing smokers on NDPs with sudden cravings to smoke occasionally. The numbers of such smokers is suggested by the relative success of Zyban, the one NDP that is labeled to permit occasional smoking while on the treatment. Many smokers are clearly daunted by the all or nothing choice that NDPs now put to them.

More importantly, exposure reduction claims would target those smokers who are not ready to quit but are looking to reduce their cigarette intake. A major objection to exposure reduction claims is that the FDA would then be approving a drug for the purpose of maintaining a smoking habit, albeit at a reduced level, which can by no means be defined as “safe.” However, the FDA has shown flexibility in this area by defining safety in a relative sense, as compared with the risks posed by the untreated disorder or disease. Thus, chemotherapy is deemed “safe” treatment for those with cancer. In this instance, too, the benchmark for safety ought not to be the non-smoker, but the addicted smoker. And if NDPs can facilitate significant exposure reduction, then they are unquestionably safer than no treatment. Studies are now beginning to document the health benefits of exposure reduction for heavily addicted smokers. An American Cancer Society study found that, among fifty year old smokers of forty or more cigarettes per day, cutting out twenty cigarettes a day added an average of one year to the participants’ lives. Among similar smokers at age 30, cutting their exposure in half added close to two years to their lives. And cutting their exposure by more than 75% (to less than ten cigarettes a day) added an average of 4.7 years.<sup>30</sup> Thus the health benefits of allowing NDPs to market themselves as exposure reduction products could be enormous.

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<sup>30</sup>Id. at 80 (citing David M. Burns, *Estimating the Benefits of a Risk Reduction Strategy*, Poster Session at the Third Annual Conference of the Society for Research on Nicotine and Tobacco, Nashville, TN (June 13-14, 1997)).



A concern of the FDA is that allowing NDPs to market themselves as exposure reduction products are unclear. It is feared that smokers will accept exposure reduction as an independent health goal and give up on abstinence. The problem with playing the all-or-nothing game, however, is that the statistics on quitting smoking are not encouraging that “all” is accessible, or at least accessible on a first try. Of the 17 to 22 million smokers who try to quit every year, more than 97% eventually relapse. With the help of NDPs, the number of successful long-term quitters might be raised as high as 5 or 6%. Thus, forcing all concerned smokers into a binary world of full-throttle smoking or abstinence relegates the vast majority of those who try to quit to failure. And failure can be disheartening and discourage future efforts to quit or reduce exposure. Allowing smokers to aim for exposure reduction with the help of treatment products would place much more accessible goals before smokers and reinforce the notion that they can successfully exert self-control and change their habits.

Another risk of encouraging exposure reduction claims is that it might provide a less-optimal goal for smokers who would have been able to quit in a binary world. But with the great bulk of quitting attempts ending in failure, it seems more important to concentrate on aiding the 97% – allowing them to smoke during their cessation attempts and providing a realistic goal for those who are not yet ready to quit.

Finally, allowing NDP manufacturers to make exposure reduction claims is not likely to lead to any increase in youth experimentation with NDPs. Thus, this is an area in which a change in FDA regulation could increase health benefits for smokers without weakening its prevention efforts.

A second major opportunity for productive regulation in this field is allowing fast-track approval for NDPs. This would require that the FDA treat tobacco addiction as a life threatening disease. While tobacco addiction is not directly life threatening, a more broad perspective would allow the FDA to classify it as such on the basis of the deathly cancers that accompany the great majority of tobacco addictions.

Granting NDPs fast-track status would allow their manufacturers to test for surrogate end-points, such as reduced exposure to contaminants and toxins, rather than clinical end-points, such as reduced risk of lung cancer, in their clinical trials.<sup>31</sup> The benefits of this move would be significant. It would mean that new products, new indications, and new doses, could come to market more cheaply and quickly. New delivery systems, doses, and products could be a boon to addicted smokers, many of whom have particularized difficulties in quitting and would benefit from more diverse and targeted treatment options. Surrogate end-points would also facilitate the approval of exposure reduction claims, discussed above, whose health benefits have yet to be clinically documented.<sup>32</sup>

Moreover, fast-track approval would make the NDP sector more appealing to potential manufacturers considering entering the market and more efficient for those already in it, thus driving prices down. This would be an enormous benefit to smokers, who face steep costs when they consider attempting to quit with the aid of an NDP. To complete the course of treatment at a minimum dose level, a consumer using the Nicoderm patch or Nicorette gum would pay approximately \$222. A consumer choosing Zyban (bupropion) would pay approximately \$125. These costs are rarely covered by health insurance companies. Admittedly, smoking itself is a costly proposition, and a year of smoking one pack a day would cost about \$900. But the disparity between the high, up-front costs of NDPs and a cheap three dollar pack of cigarettes, can be a serious disincentive to smokers, especially when they have doubts that the treatment will even work for them.

Of course, there would be costs inherent in fast-track approval. Lowering the bar for pre-market research is

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<sup>31</sup>Joseph A. Page, *Federal Regulation of Tobacco Products and Products that Treat Tobacco Dependence: Are the Playing Fields Level?*, 53 FOOD & DRUG L.J. 11, 21 (1998).

<sup>32</sup>Kenneth E. Warner et al, *Treatment of Tobacco Dependence: Innovative Regulatory Approaches to Reduce Death and Disease: Preface*, 53 FOOD & DRUG L.J. 1, 7 (1998).

always accompanied by increased risks. But, in this instance, the staggering death toll of tobacco suggests that fast-track approval for NDPs is appropriate, as it is in the comparably fields of AIDS and cancer treatments.

Another cost would be that NDPs would become more attractive to non-smokers as their price fell. Here the zero-sum fears are justifiably raised, as, at some level, every reduction in price will risk a concomitant increase in non-smoker demand. There are two mitigating factors, however. First, the price of NDPs is currently much higher than that of tobacco products. In a recent trip to a pharmacy, I observed that no over-the-counter NDP is available for less than \$29. Significant reductions in price would be possible before NDPs became a serious competitor for the dollars of non-smokers. Second, should market forces push the price of NDPs to a point where the FDA perceived a real problem, it could raise prices to an artificially high level through regulation.<sup>33</sup>

## **Conclusion**

There is a great need for the increased development and use of NDPs in this country. A creative regulatory approach, such as the FDA brought to tobacco regulation, could do an enormous amount of good.

In the field of NDPs, as in every area of drug regulation, a new regulatory approach will bring with it costs and benefits. Some of these trade-offs are outlined above while others will not, and cannot, be known until the changes are actually implemented. Research in this new field is urgently needed to develop our knowledge of the effects of NDPs further, and to test fears and hypotheses about such topics as exposure reduction and the prevalence of NDP use among non-smokers.

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<sup>33</sup>One such option would be mandating minimum amounts of product per package.

But, in the interim, as our knowledge advances, the FDA should not be slow to adopt the same aggressive yet flexible approach to NDPs that it has adopted towards tobacco. It should be a short-term goal for the FDA to ensure that “each decision to smoke should present an equal opportunity not to smoke and an equal opportunity to get help.”<sup>34</sup>

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<sup>34</sup>C. Everett Koop, *Let's Not Forget About Helping Out Older Smokers, Too*, HOUS. CHRON., March 15, 1998.